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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,216

04/01/2004

Andrew Peter Phelan

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06/29/2005

FOLEY HOAG, LLP
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EXAMINER

CHISDES, SARAH J

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/816,216

Applicant(s)

PHELAN, ANDREW PETER

Examiner

Sarah J. Chisdes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/1/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on June 4, 2003. It is noted, however, that applicant has not filed a certified copy of the 0312802.2 application as required by 35 U.S.C. 119(b).

Information Disclosure Statement

The Information Disclosure Statement submitted on April 1, 2004 has been received. An initialed, signed and dated copy of it is included with this Office action.

Drawings

The drawings submitted on April 1, 2004 have been received and entered of record into the file. The drawings are acceptable.

Claim Objections

Claim 3 is objected to because of the following informalities: In line 1, the claim recites two photodetectors positioned on opposite "sizes" of the at least one zone. The examiner assumes that "sides" was the intended word, and has examined the claim accordingly.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding claims 10, 11, and 12, the phrase "no larger than about" renders the claim indefinite because it is unclear what range of specificity "no larger than about" encompasses. See MPEP § 2173.05(b). The phrase "no larger than" would be acceptable or the word "about" would be acceptable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(f) he did not himself invent the subject matter sought to be patented.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-3, 5, 7, 9, 16-18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Markart (US 5,889,585).

Regarding claims 1 and 7, Figure 1 of Markart discloses two light sources (22 and 24), meeting the limitation of "at least one light source", capable of emitting light incident on two spatially separated zones of a test strip (26 and 28), and a photodetector (30), thereby meeting the

limitations of claim 1, wherein the detector is positioned between the spatially separated zones and laterally offset from the zones, thereby meeting the limitations of claim 7.

Regarding claims 2, 3, and 16, Figure 4 of Markart discloses two light sources (22 and 24), and two detectors (36 and 38), wherein the detectors are positioned to detect at least a portion of the light emanating from at least one zone, thereby meeting the limitations of claim 2, and wherein the detectors are positioned on opposite sides of the at least one zone and laterally offset from the at least one zone, thereby meeting the limitations of claim 3. The limitations of claim 16 are met by the two light sources (22 and 24), meeting the limitation of "at least one light source", capable of emitting light onto two zones of the test strip (26 and 28), meeting the limitation of "at least one zone of the test strip", and the two detectors (36 and 38), each of which detects light emanating from at least one zone of the test strip.

Regarding claim 5, Markart discloses in column 3 lines 26-27, that the light sources are light emitting diodes.

As to claim 9, in column 2 lines 47-48, Markart provides a housing to contain "a measuring optic system", among other things, and in column 3 lines 27-34 defines the measuring optic system as comprising the light sources and the detector, thereby meeting the limitations of claim 9.

Claim 17 describes a method for using the device claimed in claims 1 and 9, and is therefore not patentably distinct. Claim 17 is rejected as set forth above in regard to claims 1 and 9.

Claim 18 is dependent on claim 17 and further specifies that the test strip is at least partially inside the assay result reader. In the description of the housing in column 2 lines 47-49,

Markart includes a "strip support for the test strip", thereby allowing the test strip to be at least partially contained within the housing, and meeting the limitation of claim 18.

In regard to claim 20, Markart discloses a housing (in column 2 lines 48-56) with a strip support and a measuring optic system, where the measuring optic system has two light sources and two detectors for measuring two spatially separated zones of a test strip. The two light sources meet the limitation of "at least one light source", and the use of the device described by Markart would constitute the method described in claim 20, thereby meeting the limitations of claim 20.

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Eisenmann et al. (US 6,825,918). Figure 2 of Eisenmann discloses two light sources (22 and 24), meeting the limitation of at least one light source, capable of emitting light onto two spatially separated zones of a test strip (26 and 28), and a photodetector (30) which detects light emanating from each of the two zones, thereby meeting the limitations of claim 1. Eisenmann further teaches in column 4 lines 33-46, that the number of light sources can be the same as the number of zones to be analyzed, and gives an example of four zones being analyzed. Because it is possible to use four light sources to analyze four zones of a test strip, it logically follows that three light sources would be used to measure three zones of a test strip. If the "at least two zones of the test strip" is taken to be three zones (three is "at least two"), it logically follows that three light sources would be used, thereby meeting the limitation of the light source comprising three light sources of claim 4.

The inventions of Markart and Eisenmann are directed to the same problem solving endeavor, have a common assignee, and have many elements in common. Many of the claims

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rejected as being anticipated by Markart could also have been rejected as being anticipated by Eisenmann.

Claims 1 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolduan et al. (US 6,055,060). Figure 1 of Bolduan discloses two light sources (L_1 and L_2), meeting the limitation of at least one light source, capable of emitting light onto two spatially separated zones of a test strip (B_1 and B_2), and a photodetector (D) which detects light from each of the two zones, thereby meeting all the limitations of claim 1. Bolduan further discloses in column 5 lines 25-27 that the photodetector, which is termed a sensor, can be a photodiode, thereby meeting the limitation of claim 6 that the photodetector be a photodiode.

Claims 1-2, 4-6, 9-13, and 15-20 are directed to the same invention as that of claims 1, 3-6, 9-12, 14, and 16-17 of commonly assigned application number 10/742,459, and claim 14 is directed to the same invention as that of claims 1, 4, and 5 of commonly assigned application number 10/741,416. These three applications all stem from the same provisional application (60/508,001), which names two inventors. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved. Due to the similarity of the three inventions, the examiner is unable to determine which individual is the inventor of each invention, or if both individuals are co-inventors of each invention.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more

than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Markart.

Markart discloses a housing to contain the light sources and detectors, among other elements, in column 2 lines 47-56. Markart does not disclose the dimensions of the housing, nor the size of the area in which the light source and detector are located. It would have been obvious to one of ordinary skill in the art at the time of invention to package the assay reading device in a housing of convenient size for holding in one hand, and to dispose the light source and detector in close proximity to each other since it has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device, and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), MPEP 2144.04-IV-A.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 4-6, 9-13, and 15-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-6, 9-12, 14 and 16-17 of copending application number 10/742,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same elements used for the same functions are contained in both sets of claims. The present application (referred to as '216) claims an assay reading device for a test strip. The copending application (referred to as '459) claims an assay reading device for a liquid transport carrier. A test strip is a specific type of liquid transport carrier, and therefore the more specific claims of '216 are not patentable over the more general claims of '459. The elements and steps are not claimed in the same order with the same dependencies, but all the elements of the above mentioned claims of '216 are claimed in the above mentioned claims of '459. Since each application contains only one invention, all the elements are considered to be used together and the ordering and dependencies in which they are claimed are not substantive.

All the elements of claim 1 of '216 are contained in claim 1 of '459.

The elements of claim 2 of '216 are described in claims 5 and 6 of '459, where the detectors positioned to detect at least a portion of the light emanating from at least one zone of the test strip of '216, are included in the first detector receiving light from the first zone and the second detector receiving light from the second zone of '459.

The elements of claim 4 of '216 are described in claim 17 of '459 which describes a reader with three light sources.

The elements of claims 5 and 6 of '216 are met by claims 3 and 4 of '459 which specify the light source as a light emitting diode (LED) and the detector as a photodiode.

Claims 9-12 of '216 specify the same limitations on the housing and arrangement of devices therein as in claims 9-12 of '459.

Claim 13 of '216 is met by the elements of claim 1 of '459.

The elements of claim 15 of '216 are contained in claim 1 of '459.

The limitations of claim 16 of '216 are met by claims 5 and 6 of '459, where the limitation that each detector receives light from at least one zone of the test strip is met by the first detector receiving light from the first zone of the test strip and the second detector receiving light from the second zone of the test strip in '459.

The elements of claims 17 and 18 of '216 are contained in claims 14 and 16 of '459.

The limitations of claim 19 of '216 are contained in claim 17 of '459.

The elements of claim 20 of '216 are contained in claim 14 of '459, where it is understood that a light level at the photodetector is measured in '459 even though it is not specified, in order to obtain the specified signal.

Claim 14 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 5 of copending application number 10/741,416. Although the conflicting claims are not identical, they are not patentably distinct from each other because the same elements used for the same functions are contained in both sets of claims. The present application (referred to as '216) claims an assay reading device for a test strip. The copending application (referred to as '416) claims a device for reading the result of an assay, but does not specifically claim that the assay is performed using a test strip. An assay performed using a test strip is a specific type of assay, so the more specific claim of '216 is not patentable over the more general claims of '416. The elements are not claimed in the same order with the same dependencies, but all the elements of claim 14 (and claim 1 on which it depends) of '216 are contained in claims 1, 4, and 5 of '416. Since each application contains only one invention, all the elements are considered to be used together and the ordering and dependencies in which they are claimed are not substantive.

Claim 14 of '216 describes a computation circuit and its use within the optical device of claim 1 of the same application. Claim 1 of '416 describes a computation circuit to perform the same steps as the computation circuit of claim 14 of '216. Claims 4 and 5, which are dependent on claims 1 and 4 respectively, of '416 specify the optical elements claimed in claim 1 of '216. Therefore claims 1, 4, and 5 of '416 taken together constitute the same device as that claimed in claims 1 and 14 of '216 taken together.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

Claim 8 is allowed. Claims 13, 14, 15, and 19 would be allowable if the matters address by the provisional non-statutory double patenting, 102 (f) or (g) rejections are overcome as set forth above.

The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record taken alone or in combination fails to disclose a test strip reader where three light sources are used to illuminate three zones of a test strip, and where two detectors are shared among the zones to collect light from the three zones, as claimed with the elements and steps of claim 19, along with baffles to prevent the light sources from illuminating more than two zones, as further claimed with the elements of claim 8. Markart and Eisenmann both disclose two light sources and a shared detector, but do not expand it to three light sources and two shared detectors. Eisenmann teaches the use of three light sources, but uses the same number of detectors as light sources. Strohmeier (US 4,676,653) uses baffles to control which areas of a test strip are illuminated by each light source, but uses two independent detectors for the two light sources. The use of three light sources allows for the independent illumination and therefore analysis of three areas or zones of a test strip, which, in turn, allows for a better understanding of how well the assay has been performed. Using two strategically located detectors instead of three when using three light sources enables the device to be produced less expensively, since detectors tend to be an expensive component.

Additionally, the prior art of record taken alone or in combination fails to disclose a method or device whereby the validity of an assay performed on a test strip is determined by monitoring the flow rate of the fluid on the liquid transport carrier as recited in combination with

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the elements and steps of claims 13 and 15. The prior art does not disclose an optical device or method for monitoring the flow rate of a fluid on a liquid transport carrier. Pan et al. (US 2002/0192833 A1) teaches monitoring the presence or absence of fluid on a test strip as a function of time, but does not determine the flow rate of the fluid. Markart discloses measuring changes in light transmittance or reflectance in two zones of a test strip at repeated time intervals, but does not use this information to calculate a flow rate. Tajnafoi (US 6,448,067) monitors the intensity of reflected light from a test strip over a period of time, and determines when wetting occurs, but does not use this information to calculate a flow rate.

Additionally, the prior art of record taken alone or in combination fails to disclose a method or device whereby the amount of analyte or the rate of accumulation of analyte is compared to upper and lower thresholds in order to determine the validity of the assay as recited with the elements and steps of claim 14. Bolduan compares two measured values and determines if the difference between them is below a threshold in order to determine the validity of assay, but does not compare either value to both an upper and lower threshold. Eisenmann compares two values and determines if a relationship between the two values exceeds a threshold. Markart also compares two values and relates them to a threshold, but does not determine if either value is within a specified range.


Contact Information

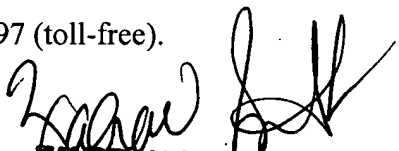
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah J. Chisdes whose telephone number is 571-272-8540. The examiner can normally be reached on 9am -6:30pm Monday through Thursday and 9am - 5:30pm on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley Jr. can be reached on 571-272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


S.J. Chisdes, Ph.D.
June 16, 2005


ZANDRA V. SMITH
PRIMARY EXAMINER